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Date of Deposit: July 15, 2003

I hereby certify that this paper (along with any referred to as being attached or enclosed) is being deposited with the United States Postal Service in an envelope as "Express Mail" addressed to the Mail Stop Patent Application, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

  
Laura Lee Mosier

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of:

DAVID E. SILVERMAN *et al.*

Application No. Not yet assigned

Filed: Herewith

For: Method for Treating Fecal  
Incontinence

Art Unit: Not yet assigned

Examiner: Not yet assigned

Date: July 15, 2003

**INFORMATION DISCLOSURE STATEMENT**

Mail Stop Patent Application  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

Applicant submits herewith patents and publications which may be material to the examination of this application and in respect of which there may be a duty to disclose in accordance with 37 C.F.R. §1.56. While this Statement may be "material" pursuant to 37 C.F.R. §1.56, it is not intended to constitute an admission that any patent, publication, or other information referred to therein is "prior art" for this invention unless specifically designated as such.

Enclosed herewith are PTO/SB/8A & SB/8B forms listing art potentially relevant or of interest to the referenced patent application. This application relies on the earlier filing dates of prior Application Nos. 09/882,522, filed June 15, 2001; 09/286,245, filed April 5, 1999 and 09/232,056 filed January 15, 1999, under 35 U.S.C. § 120. It is understood that the Examiner will consider information that was submitted to or cited by the Office in such prior applications. Notice of April 20, 1992; 1138 OG 37-41, at 37. Copies of documents previously submitted to or cited by the Office in the prior applications are not required to be provided in this application and thus are not attached. 37 C.F.R. § 1.98(d).

This information disclosure statement is being filed in compliance with 37 CFR 1.97(b)(3) as being filed before the mailing date of the first office action on the merits.

Should any questions or comments arise regarding the listing of the submitted publications and patents in which the Examiner feels a telephone conversation would be appropriate, he or she is respectfully requested to contact the undersigned attorney at the listed telephone number.

Respectfully submitted,

DORSEY & WHITNEY LLP

A large, stylized handwritten signature in black ink, appearing to read 'EDWARD N. BACHAND', is written over the printed name.

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1060473

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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>				<i>Complete if Known</i>		
				Application Number	To be assigned	
				Filing Date	July 15, 2003	
				First Named Inventor	DAVID E. SILVERMAN	
				Group Art Unit	To be assigned	
				Examiner Name	To be assigned	
Sheet	1	of	3	Attorney Docket Number	A-70013-1/ENB	
<b>U.S. PATENT DOCUMENTS</b>						
Examiner Initials <sup>1</sup>	Cite No. <sup>1</sup>	U.S. Patent Document	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	
		Number Kind Code <sup>2</sup> (if known)				
	A1	3,094,122	Gauthier et al.	06/18/1963		
	B1	3,204,634	Koehn	09/07/1965		
	C1	4,351,333	Lazarus et al.	09/28/1982		
	D1	4,424,208	Wallace et al.	01/03/1984		
	E1	4,582,640	Smestad et al.	04/15/1986		
	F1	4,773,393	Haber et al.	09/27/1988		
	G1	4,803,075	Wallace et al.	02/07/1989		
	H1	4,837,285	Berg et al.	06/06/1989		
	I1	5,007,940	Berg	04/16/1991		
	J1	5,067,965	Ersek et al.	11/26/1991		
	K1	5,116,387	Berg	05/26/1992		
	L1	5,158,573	Berg	10/27/1992		
	M1	5,204,382	Wallace et al.	04/20/1993		
	N1	5,258,028	Ersek et al.	11/02/1993		
	O1	5,301,682	Debbas	04/12/1994		
	P1					
	Q1					
	R1					
<b>FOREIGN PATENT DOCUMENTS</b>						
Examiner Initials <sup>1</sup>	Cite No. <sup>1</sup>	Foreign Patent Document	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant	T <sup>6</sup>
		Office <sup>3</sup> Number <sup>4</sup> Kind Code <sup>2</sup> (if known)				
	S1	WO 98/17201	PCT	04/30/1998		
	T1	WO 98/17200	PCT	04/30/1998		
	U1	WO 98/01088	PCT	01/15/1998		
	V1	WO 97/45131	PCT	12/04/1997		
	W1	WO 97/19643	PCT	06/05/1997		
	X1	AU A-34223/95	AU	05/02/1996		
	Y1					
	Z1					
Examiner Signature				Date Considered		

<sup>1</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>2</sup> Unique citation designation number. <sup>3</sup> See attached Kinds of U.S. Patent Documents. <sup>4</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3).

<sup>5</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>6</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible.

<sup>7</sup> Applicant is to place a check mark here if English Language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231.

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		Number Kind Code <sup>2</sup> (if known)				
	A2	5,336,263	Ersek et al.	08/09/1994		
	B2	5,451,406	Lawin et al.	09/19/1995		
	C2	5,480,644	Freed	01/02/1996		
	D2	5,490,984	Freed	02/13/1996		
	E2	5,580,568	Greff et al.	12/03/1996		
	F2	5,667,767	Greff et al.	09/16/1997		
	G2	5,695,480	Evans et al.	12/09/1997		
	H2	5,702,361	Evans et al.	12/30/1997		
	I2	5,755,658	Wallace et al.	05/26/1998		
	J2	5,785,642	Wallace et al.	07/28/1998		
	K2	5,792,478	Lawin et al.	08/11/1998		
	L2	5,830,178	Jones et al.	11/03/1998		
	M2	6,251,063	Silverman et al.	06/26/2001		
	N2	6,251,064	Silverman et al.	06/26/2001		
	O2	2001/0018548	Silverman et al.	08/30/2001		
	P2					
	Q2					
	R2					
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		Kind Code <sup>2</sup> Office <sup>3</sup> Number <sup>4</sup> (if known)				
	S2					
	T2					
	U2					
	V2					
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Sheet	3	of	3	Attorney Docket Number	A-70013-1/ENB
<b>OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS</b>					
Examiner Initials <sup>1</sup>	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.			T <sup>2</sup>
	A3	Donahue, P. et al., "Endoscopic Sclerosis Of The Gastric Cardia For Prevention Of Experimental Gastroesophageal Reflux" (1990) <i>Gastrointestinal Endoscopy</i> , pp. 253-256.			
	B3	Klingman, R.R. et al., "The Current Management of Gastroesophageal Reflux", (1991), <i>Adv. Surg.</i> , Vol. 24, pp. 259-291.			
	C3	Malizia, A. et al., "Migration and Granulomatous Reaction After Periurethral injection of Polytef (Teflon)", (June 1984), <i>JAMA</i> , Vol. 251, No. 24, pp. 3277-3281.			
	D3	O'Connor, K.W. et al., "Endoscopic placement of collagen at the lower esophageal sphincter to inhibit gastroesophageal reflux: a pilot study of 10 medically intractable patients", (1988), <i>Gastrointestinal Endoscopy</i> , Vol. 34, No. 2, pp. 106-112.			
	E3	O'Connor, K. W. et al., "An experimental endoscopic technique for reversing gastroesophageal reflux in dogs by injecting inert material in the distal esophagus", (1984) <i>Gastrointestinal Endoscopy</i> , Vol. 30, No. 5, pp. 275-280.			
	F3	Ortiz, A. et al., "Conservative treatment versus antireflux surgery in Barrett's oesophagus: long-term results of a prospective study", (1996), <i>Brit. Jnl. of Surg.</i> , Vol. 83, 274-278.			
	G3	Politano, V.A., et al., "Periurethral Teflon Injection for Urinary Incontinence", (February 1974) <i>Jnl. Urology</i> , Vol. 111, pp. 180-183.			
	H3	Schulman, C.C. et al., "Endoscopic injections of Teflon to treat urinary incontinence in women", (January 21, 1984) <i>BMJ</i> , Vol. 228, p. 192.			
	I3	Shafik, A., "Intraesophageal Polytef injection for the treatment of reflux esophagitis", (1996), <i>Surgical Endoscopy</i> , pp. 329-331.			
	J3	Walker, R.D. et al., "Injectable Bioglass as a Potential Substitute for Injectable Polytetrafluoroethylene", (August 1992), <i>J. Urol.</i> , Vol. 148, pp. 645-647.			
	K3				
	L3				
	M3				
	N3				
	O3				
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